Form approved: OMB No. 0910-0397
Expiration Date: February 29, 2000
See OMB Statement on reverse

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, Federal Y2K Biomedical Equipment Clearinghouse

Additional Information Request Form – Manufacturer Reporting Y2K Compliant Products – FORM FDA 3473

Please verify and correct, or provide any missing information and return as indicated in the enclosed **Options for Reporting** page.
For detailed instructions, please refer to the appropriate line number on the **BACK** of this form.

Line #	Manufacturer Information	
1.	Manufacturer Name	
2.	Division *(see instructions on the back of the form)*	
3.	Enter Your FDA Assigned Owner/Operator Number	
	Contact Information	
4.	Y2K Contact's Name *(First and Last)*	
5.	Y2K Contact's Address	
6.	Y2K Contact's City, State/Province and Postal Code	
7.	Y2K Contact's Country	
8.	Y2K Contact's Telephone	
9.	Y2K Contact's Fax	
10.	Y2K Contact's Email	
	Y2K Status Information	
11.	In addition to the Y2K status information previously provided, your company is requested to report all products that are Y2K compliant. Please see Line #12 for the options available for reporting medical devices and/or scientific research equipment that are Y2K compliant.	
	Additional Information	
12.	Use one of the three options below to report medical devices and/or scientific research equipment that are Y2K compliant to the Clearinghouse: (1) Paper Reporting – Complete a **Compliant Products – FORM FDA 3474** for each product that is Y2K compliant. (2) Online at FDA's Web Site – http://www.fda.gov/cdrh/yr2000/y2kform.html (3) Electronic File Submission (E-File) – Please see the enclosed instructions entitled, **Options for Reporting Biomedical Equipment That Is Y2K Compliant**. For details about each option, please see the enclosed instructions entitled **Options for Reporting Biomedical Equipment That Is Y2K Compliant**.	

INFORMATION CURRENT AS OF 9/15/1999

Federal Y2K Biomedical Equipment Clearinghouse
Instructions – FORM FDA 3473

This form has been filled-in with the information your company has provided, if applicable. Please verify and correct, or provide any missing information and return as indicated in the enclosed **Options for Reporting** page.

If you have questions about completing this form or the Federal Y2K Biomedical Equipment Clearinghouse please call toll free 1-877-744-1522 between 8:30am and 5:00pm Monday through Friday Eastern Time, or Email the Y2K Clearinghouse at y2kstatus@bah.com. You may also fax your completed forms to 1-301-881-1848.

Line Number Key

Manufacturer Information	
1. Manufacturer Name	Name of the Manufacturer submitting the product information.
2. Division(s)	Name of the Division, if this report is for ONE specific division. Complete ONE form for each division that manufactures biomedical equipment. Please leave blank if you are reporting for the entire company.
3. Enter Your FDA Assigned Owner/Operator Number	If the Manufacturer submitting Y2K compliance information is FDA regulated, please enter your FDA assigned Owner/Operator Number.
Contact Information	
4. Y2K Contact's Name *(First and Last)*	First and Last Name of the Y2K contact for the manufacturer.
5. Y2K Contact's Address	Mailing address of the Y2K contact.
6. Y2K Contact's City, State/Province and Postal Code	City, State, Province, and Postal Code of the Y2K contact.
7. Y2K Contact's Country	Country location of the Y2K contact.
8. Y2K Contact's Telephone	Telephone number of the Y2K contact.
9. Y2K Contact's Fax	Fax number of the Y2K contact.
10. Y2K Contact's Email	E-mail address of the Y2K contact.
Y2K Status Information	
11. In addition to the Y2K status information previously provided, your company is requested to report all products that are Y2K compliant. Please see Line #12 for the options available for reporting medical devices and/or scientific research equipment that are Y2K compliant.	
Additional Information	
12. Additional Information	Use one of the three options below to report medical devices and/or scientific research equipment that are Y2K compliant to the Clearinghouse: (1) Paper Reporting – Complete a **Compliant Products - FORM FDA 3474** . (2) Online at FDA's Web Site – http://www.fda.gov/cdrh/yr2000/y2kform.html (3) Electronic File Submission (E-File) – Please see the enclosed instructions entitled, **Options for Reporting Biomedical Equipment That Is Y2K Compliant**. For details about each option, please see the enclosed instructions entitled **Options for Reporting Biomedical Equipment That Is Y2K Compliant**.

Public reporting burden for this collection of information is estimated to average .5 hours per response, including the time for reviewing instructions, search existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Year 2000 Coordinator (HFZ-Y2K)
Center for Devices and Radiological Health, FDA
9200 Corporate Boulevard
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

YEAR 2000 READINESS DISCLOSURE